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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/724,910

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Hugh J. Pasika

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06/30/2006

MILA KASAN, PATENT DEPT.  
APPLIED BIOSYSTEMS  
850 LINCOLN CENTRE DRIVE  
FOSTER CITY, CA 94404

EXAMINER

WHALEY, PABLO S

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 06/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/724,910	<b>Applicant(s)</b> PASIKA ET AL.	
	<b>Examiner</b> Pablo Whaley	<b>Art Unit</b> 1631	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03/29/2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 46-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 46-51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### *REQUEST FOR CONTINUED EXAMINATION*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/29/2006 has been entered.

### *CLAIMS UNDER EXAMINATION*

Claims herein under examination are Claims 46-51. Claims 1-45 have been cancelled. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### CLAIM REJECTIONS - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 46-51 are rejected under 35 U.S.C. 101 because these claims are drawn to non-statutory subject matter. Claims 46-51 are directed to a method and computer readable medium for processing fragment analysis data, which do not recite either a physical transformation of matter nor a practical application [i.e. concrete, tangible, and useful result]. Instant claims 46 and 51 recite steps drawn to receiving data, presenting data, performing analysis, and reporting analysis results. As the Specification does not provide limiting definitions such that these steps are necessarily physical steps, the claim does not result in a physical transformation of matter. It is noted that the specification does provide a limiting definition such that a "computer-readable medium" is necessarily a physical medium. As claim 51 is directed to a program (instructions) residing on a computer readable medium, wherein the medium is not necessarily physical, the determination of whether the claims are statutory depends on whether the method encoded is statutory. Where a claimed method does not result in a physical transformation of matter, it may be statutory where it recites a concrete, tangible, and useful result (i.e. a practical application). However, no actual, concrete result is recited in the claims, nor is any useful result "produced" in a tangible form useful to one skilled in the art. For these reasons, the claims are not statutory. For an updated discussion of statutory considerations with regard to non-functional descriptive material and computer-related inventions, see the Guidelines for Patent Eligible Subject Matter at 1300 OG 142, Annex IV, Nov. 22, 2005.

**NEW MATTER**

Claims 46-51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

Amended claims 46 and 51 recite a "two-stage allele caller", "a first stage that determines if data is in a second stage's operating range", and "a second stage that is configured to perform a second analysis that determines allele calls." These limitations are new matter as they are not taught in the specification and are not present within the scope of the original claims as filed. It is noted that the original claims as filed and the specification are silent with regard to the term "stage." Original claim 1 recites the limitation "applying at least two different allele calling algorithms", but this is not support for a "two-stage allele caller." The specification discloses "multiple allele calling algorithms" and a "committee machine" that receives allele calls from multiple algorithms, but this is not support for a *two-stage allele caller*. For these reasons, claims 46-51 are rejected as they introduce NEW MATTER.

**CLAIM REJECTIONS - 35 USC § 112, 2<sup>nd</sup> Paragraph**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 46-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 46 and 51 recite the limitations "two-stage allele caller." As the specification does not define or fully and completely describe a "two-stage allele caller," it is unclear whether "two-stage allele caller" is intended to refer to an algorithm, a panel, a step, or something else. Clarification is requested. Applicant is reminded that a method of "calling alleles" or otherwise processing signals comprising applying two different allele calling programs and "assigning a confidence level"; i.e. determining whether data are correctly placed, falls within a nonelected category of invention, therefore claims reciting these or similar limitations may be considered nonelected, and may be withdrawn. See the Restriction Requirement of 1/15/02. Applicant is also reminded that he may not "switch" inventions in an RCE.

Claims 46 and 51 recite the limitations "first stage" and "second stage." As the specification does not define or fully and completely describe "stage," it is unclear whether "stage" is intended to refer to an algorithm, a panel, a step, or something else. Clarification is requested.

Claims 46 and 51 recite the limitation "operating region." As the specification does not define or fully and completely describe "operating region", it is unclear whether "operating

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region" represents a threshold, a numerical value, a distance, or something else. Clarification is requested. Claims 47-50 are rejected as they depend directly or indirectly from instant claim 46.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following prior art publications are the basis for executing this rejection:

Claims 46, 47, and 51 are rejected under 35 USC § 102(e) as being anticipated by Perlin (US #6,807,490; filed Feb. 15, 2000).

Applicant's arguments, filed 02/09/2006, that Perlin does not anticipate the instant invention on the grounds that applicant's threshold test does not perform allele calling but rather serves to screen data are not deemed to be persuasive. This argument is moot as applied to claim 47, as amended claim 47 does not recite a "threshold test" nor any other limitation with regard to a "threshold". Further, the instant claims do not recite "screening" but do specifically recite presenting data to a two-stage allele-caller (claim 46) and defining first and second alleles

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(claim 49). The last step of claim 48 specifically recites "calling alleles," therefore the argument that the claims are not directed to allele calling appears to contradict the actual limitations recited in the claims. In addition, Perlin discloses that in genotyping applications, allele calling is a distinct analysis that should only be done on the signals after corrections (e.g. for stutter or relative amplification) have been made [Col. 24, lines 25-35]. As stated in the previous office action, mailed Dec. 17, 2004, Perlin teaches removal of peaks from the signal that either (a) have a DNA length that is not in a window of the allelic ladder, or (b) have a DNA amount that is not within some minimum percentage of the largest peak prior to allele calling. Therefore, screening of data (i.e. via peak removal) is inherently taught by Perlin. Allele calling is done by matching the DNA lengths of each sample peak to the DNA sizing windows on the allelic ladder [Col. 24, lines 40-55].

Applicant's arguments, filed 02/09/2006, that Perlin does not anticipate the instant invention on the grounds that the "DNA sizing" windows taught by Perlin do not correspond to the "panels" of the instant application are not deemed to be persuasive because claim 47 merely recites dividing a first signal into "panels" wherein the boundaries are minima of the signal, which is what Perlin teaches by dividing the sizing data into windows (i.e. panels) divided by minima of size peaks (see below).

Perlin teaches a method and system for analyzing DNA fragments from a nucleic acid sample [Col. 29, lines 60-67], as in instant claims 46 and 51. The system further comprises means for detecting sample DNA fragments to form signals representing size and intensity [Col. 29, lines 60-67 and Fig. 6], as in instant claims 46 and 51. More specifically, Perlin et al. teach the following aspects of the instantly claimed invention:



- Determining the largest peaks (i.e. area or height) in allelic ladder windows (i.e. panels) [Col. 24, lines 45-55], which correlates to a first analysis in a first stage for determining one or more maxima as in instant claims 46, 47, and 51.
- Calling alleles by matching DNA lengths to DNA sizing windows on the allelic ladder, which correlates to a second analysis in a second stage as in instant claims 46 and 51.
- Reporting analysis and allele calling results [Figs. 6-8], as in instant claims 46 and 51.
- Allelic windows are set around a ladder peak, typically  $\pm 0.5\text{bp}$ ; sample peaks within this bp size are designated as having lengths of the associated ladder peak [Col. 23, lines 42-50], which correlates to fragment analysis data within the second stage's operating region as in instant claims 46 and 51.
- Removal of peaks that are not within some minimum percentage of the largest peak [Col. 24, lines 40-45], which is a teaching for dividing the first signal into one or more panels located at one or more minima as in instant claim 47. It is further noted that this step correlates to reducing the dimensionality of the original signal and creation of boundaries at local minima.
- Fig. 6 displays the results of ladder processing and allele calling, where the data has been divided into eight panels, which is greater than the three panels as required in instant claim 47.

**Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 48-50 are rejected under 35 U.S.C. 103(a) as being made obvious by Perlin (US #6,807,490; filed Feb. 15, 2000), as applied to claims 46, 47, and 51, above, in view of Bahler et al. (US #4,241,329; Issued Dec. 23, 1980)

As set forth in the previous office action and reiterated above, Perlin teaches a method and system for obtaining and analyzing spectral DNA profiles obtained from a nucleic acid sample .

Perlin does not teach a "second analysis" step as in instant claims 48-50. However, Perlin suggests allele calling should only be done on the signals after corrections have been made [Col. 24, lines 25-35].

Bahler et al. teach a speech recognition method of detecting and recognizing one or more keywords in a continuous audio signal for improving false alarm rates (Abstract). More specifically, Bahler et al. teach the following aspects of the instantly claimed invention:

- Peak values of likelihood statistics (i.e. maximum spectral energy data) are determined for each of the selected patterns; Sequential selection of candidate keywords based on determination of local maximum likelihood statistics for multi-frame patterns and threshold comparison [Col. 18, lines 27-55], which correlates to defining energy panels as in instant claim 48.
- Creation of windowed spectra [Fig. 1, Step 23]; determination of peak amplitude spectral data for target patterns (i.e. spectral energy) [Fig. 1, step 87], as in instant claim 49.
- Defining first, second, and third successive spectrum members in a multi-frame pattern [Col. 12, lines 55-67], as in instant claim 48.
- Applying a continued likelihood ratio test to selected patterns corresponding to candidate keywords to determine a figure of merit (i.e. threshold) for each pattern [Ref. Claim 4 and Fig. 3, step 101], which corresponds to a first test and second test as in instant claim 48.
- Accepting candidate word if figure of merit exceeds a predetermined minimum value [Ref. Claim 4 and Fig. 3, step 107], which correlates to accepting/recognizing data if first and second tests are passed as in instant claim 48.
- Successively smoothed spectra using the FFT [Col. 9, lines 20-25], which is inherently a teaching for obtaining energy via the integral as in instant claim 50.

Thus it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to practice the correction/processing of data in different spectral windows of Bahler et al. with the DNA analysis system of Perlin, where the motivation would have been to reduce the false alarm signal detection rate as taught by Bahler et al. [Col. 18, lines 10-25]. One of ordinary skill in the art would have had a reasonable expectation of successfully combining

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the data recognition method of Bahler et al. with the DNA analysis method of Perlin because both teach analysis of spectral data.

### CONCLUSION

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached at 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pablo S. Whaley

Patent Examiner  
Art Unit 1631  
Office: 571-272-4425

**MARJORIE A. MORAN**  
**PRIMARY EXAMINER**

*Marjorie A. Moran*  
6/26/06